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From the INTERNATIONAL BUREAU

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PCTNOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)

(PCT Rule 44bis.1(c))

To:

EHRlich, Gal
G.E. Ehrlich (1995) Ltd.
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ISRAËL**RECEIVED**

23 APR 2008

FILE No. 35044

G.E. EHRlich (1995) LTD.

Date of mailing (day/month/year)

10 April 2008 (10.04.2008)

Applicant's or agent's file reference

35044

IMPORTANT NOTICE

International application No.

PCT/IB2006/053014

International filing date (day/month/year)

30 August 2006 (30.08.2006)

Priority date (day/month/year)

28 September 2005 (28.09.2005)

Applicant

DEPUY SPINE, INC., A JOHNSON & JOHNSON COMPANY et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The international Bureau of WIPO
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 35044	FOR FURTHER ACTION	See item 4 below
International application No. PCT/IB2006/053014	International filing date (<i>day/month/year</i>) 30 August 2006 (30.08.2006)	Priority date (<i>day/month/year</i>) 28 September 2005 (28.09.2005)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant DEPUY SPINE, INC., A JOHNSON & JOHNSON COMPANY		

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).																								
2.	This REPORT consists of a total of 9 sheets, including this cover sheet.																								
In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																									
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td style="width: 60%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input checked="" type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input checked="" type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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<input type="checkbox"/>	Box No. VIII	Certain observations on the international application																							
4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).																								

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 01 April 2008 (01.04.2008)
Facsimile No. +41 22 338 82 70	Authorized officer <div style="text-align: center; font-weight: bold;">Cecile Chatel</div> e-mail: pt13.pct@wipo.int

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/B2006/053014

International filing date (day/month/year)
30.08.2006

Priority date (day/month/year)
28.09.2005

International Patent Classification (IPC) or both national classification and IPC
INV. A61B17/34

Applicant
DISC-O-TECH MEDICAL TECHNOLOGIES, LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office - Gitschiner Str. 103
D-10958 Berlin
Tel. +49 30 25901 - 0
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Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Nice, Philip

Telephone No. +49 30 25901-508



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2006/053014

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2006/053014

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial
applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 20-21

because:

☒ the said international application, or the said claims Nos. 20-21 relate to the following subject matter which does not require an international search (*specify*):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for the whole application or for said claims Nos. 20-21

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2006/053014

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:
- ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-13,19

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>2-9,11,19</u>
	No: Claims	<u>1,10,12-13</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-13,19</u>
Industrial applicability (IA)	Yes: Claims	<u>1-13,19</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 20-21 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the subject-matter of these claims (Article 34(4)(a)(i) PCT).

Re Item IV

Lack of unity of invention

The document US-A-2004260303 ("D1"), which is considered the closest prior art, discloses plastically deformable cannulae with a lumen to be filled with bone filling cement at pressures of over 100 atmospheres which provides a channel of fluid communication between an injection aperture and a connector body, compared to which the special technical features of the claims in the sense of Rule 13.2 PCT are as follows:

Claims 1-13 and 19: There are a series of separate joints, or a sleeve or sealing layer

Claims 14-18: There are two or more inlet ports

The special technical features may be considered to solve the following problems:

Claims 1-13 and 19: Making the cannula easily deformable into a desired shape without permitting cement leakage.

Claims 14-18: Permitting insertion of multiple materials and/or instruments (see page 20, lines 7-14 of the description).

Since the special technical features are not the same nor, since the problems which they solve are different, are they corresponding, the inventions of the two groups of claims are not so linked as to form a single general inventive concept (Rule 13.1 PCT. Note also that page 20, lines 6-7 of the description explicitly indicate that the multiple port features and the deformable cannula features are not intended to be used together and therefore cannot possibly be considered to interact with each other.)

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 1 Reference is made to the following documents:

D1: US-A-2004260303
D2: WO-A-2005051212
D3: EP-A-1464292
D4: DE-A-4104092
D5: WO-A-2004075965
D6: WO-A-9619940

- 2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1 and 13 is not new in the sense of Article 33(2) PCT.

- 2.1 Document D1 discloses (the references in parentheses applying to this document):

A bone cement cannula (12), the cannula comprising:

(a) a tube made of stainless steel (see D1 paragraph 24), which is a ductile material and hence all sections of the tube are adapted for plastic deformation;
(b) a lumen in the tube capable of resisting forces of a viscous material propelled therethrough at a pressure of at least 100 atmospheres (see D1 paragraphs 6 and 28; 1,000-3,000 psi = 68-204 atmospheres).

- 2.2 Moreover D1 also discloses at paragraph 4 a second surgical tube i.e. cannula through which bone cement may pass, which will have to resist the same pressure, and which since it is bent to keep the user's hands or the delivery device out of the field of an imaging device must also be subject to plastic deformation. This tube too therefore constitutes a bone cement cannula with the features of claim 1.

- 2.3 Both (12) and the tube of paragraph 4 in D1 are tubes having sections adapted for plastic deformation as explained above, and their lumens are in use at least partially filled with plastic deformation. They each therefore constitute a cannula with the features of claim 13.

- 2.4 Also documents D2 and D3 each disclose a bone cement cannula (numbered (3)

in D2 and (600) in D3) comprising a tube with a lumen, including a section adapted for plastic deformation (see D2 claim 3, and D3 paragraph 34 which refers to the option of (600) being bent) i.e. with the features of claim 13.

- 3 Moreover it would be obvious to the skilled practitioner to make the devices of D2 and D3 capable of resisting a pressure of at least 100 atmospheres because such pressures are commonly used for bone cement injection, as indicated by e.g. D1, thereby arriving at the subject matter of claim 1 starting from either D2 or D3 without an inventive step in the sense of Article 33(3) PCT, contrary to the criteria of Article 33(1) PCT.
- 4 Dependent claims 2-12 do not contain any features which, in combination with the features of any claim to which refer, meet the requirements of the PCT in respect of novelty and/or inventive step, the reasons being as follows:
 - 4.1 Claim 10 refers to a use of the cannula which does not define any feature of the cannula, because for the plastically deformable section to remain outside the body does not require any feature of the cannula. Hence all features of claim 10 are known from D1 and obvious for D2-3.
 - 4.2 The term "configuration support" in claim 12 is vague and unclear, contrary to Article 6 PCT. This opinion therefore ignores it, with the consequence that D1 discloses all the features of claim 12 and they are obvious for D2-3.
 - 4.3 The subject matter of claims 2-7 differs from the prior art of each of D1-3 in that there are a series of separate joints, formed by cuts or weakening, which may facilitate a desired deformation configuration and may be sealed.

The problem solved by the subject matter of these claims is to make the cannula easily deformable, into a desired shape and without permitting cement leakage.

The skilled practitioner would combine known means of making a cannula easily deformable with any of D1-3 to arrive at the subject matter of claims 2-7. Such means, which comprise a series of separate joints are known from each of D4-6. Of these D4-5 use cuts as specified in claims 3-4 and D6 uses non-penetrating weakening as specified in claim 6. Moreover in the device of D6, the weakening being non-penetrating, the joints are sealed as required in claim 7.

- 4.4 The subject matter of claims 8-9 and 11 differs from that of each of D1-3 in that there is an outer or inner sealing layer or sleeve.

The problem solved by the subject matter of these claims is to prevent cement leakage.

The solution is obvious to the skilled practitioner because one of the examples of prior art from which he would take means for enabling plastic deformation, D4, has an outer sleeve which would act as a sealing layer (see D4 abstract). Using an inner sealing layer instead of an outer is an obvious equivalent.

- 5 Claim 19 differs from the prior art of each of D1-3 in that it constitutes the process of providing the additional features of claims 3 and 6 i.e. cuts which facilitate a desired deformation configuration. These features being for the skilled practitioner obviously desirable in the product (see section 4.3), it is obvious for the method of manufacturing the product to provide them. Hence the present application also does not meet the criteria of Article 33(1) PCT because the subject-matter of claim 19 does not involve an inventive step in the sense of Article 33(3) PCT.